deal with the interpreting physician's viewboxes, but we certainly recommend that they be similar to.

DR. BARR: Well, this recommendation is for review by the technologist also.

DR. FINDER: Right. I'm just bringing up what currently exists.

MS. RINELLA: But like what you said. How are you going to keep the technologist from turning on the overhead lights when they're actually reading films or picking up a magnifying glass and masking their films?

You know, you really can't stand there and be the mammo police, but I think the more aware I think that they are going to be made of this if we do mandate something, I think that could only help.

DR. BARR: And there is an argument to be made that when you put something in regulation, even though you can't enforce it, you know, it obviously carries more weight, but I want people to realize our limitations on some of these things that are recommended for regulation.

CHAIRPERSON HENDRICKS: I would welcome

input from the accrediting bodies as to whether these -- you know, where poor viewing conditions is a reason for failure to accredit a facility and how often that occurs. Are there instances where facilities have failed on these viewing conditions that we're discussing? And how often is that a significant issue.

Please, Penny.

MS. BUTLER: Penny Butler from the American College of Radiology.

Currently we don't fail anybody for this because it's not a regulatory requirement. Our standards for accreditation have to be essentially the same as the MQSA requirements. So even though we have it as a recommendation, it's a recommendation.

CHAIRPERSON HENDRICKS: Thank you for your comment.

DR. BARR: Thank you.

DR. MARTIN: Dr. Barr.

DR. BARR: Yes.

DR. MARTIN: Melissa Martin.

I'm sort of like Diane. We consult all

over the place. I would say at this point about 20 percent of our facilities would have to replace their light boxes. A good probably 75 to 80 percent of them are already in compliance, and I guess I'm surprised at your question of how would it be inspected because my understanding is every year the local MQSA inspector is asking the facilities to demonstrate how they mask to interpret their phantom films at this point.

Maybe that's just a local we have very aggressive inspectors, but my understanding is they ask every one of our facilities to show how they're viewing the mammography films and how do they mask off, and they want to see the brightness. They're not making measurements, but they are definitely looking at the viewing conditions every time they come into a facility.

DR. BARR: Well, do you want to comment on that?

DR. MARTIN: -- not an FDA?

DR. MOURAD: No, those are aggressive as you say inspections.

(Laughter.)

DR. BARR: This is Dr. Mourad from FDA.

DR. MOURAD: We tell them not to specifically look for those because we don't have inspection questions for them, but we also tell them if you see something totally abnormal and missing at the facility, you should bring it to their attention. Now, some of them are more zealous than others.

DR. BARR: Thank you.

Okay. So we currently don't have -- we have the physicist report. We don't have any current inspection procedures to deal with viewbox luminance. Do we think that this luminance -- do we think the numbers in this recommendation make sense, physicists?

DR. MARTIN: The numbers are fine with me.

DR. BARR: Thank you.

DR. FERGUSON: It's aggressive. Being a radiologist, I don't know numbers. So I don't know what these numbers mean literally.

(Laughter.)

DR. BARR: Well, that's why I had to ask the physicists. I'm in your boat.

DR. FERGUSON: I mean, I'd like to see in the room what kind of luminance we're talking about as far as background light to know. I wouldn't know looking at how many candela per square meter.

DR. BARR: Yes. Ms. Martin.

DR. MARTIN: If you're reading in a normal, good radiologist facility, you are nowhere close to violating these numbers. You probably are sitting in somewhere with less than six for your local -- your room luminance, illuminance.

DR. BARR: What I was glad to see is that at least there's some idea of paying attention to this, and particularly for the technologists, not just the physicians. I thought that was at least an advance.

I think we have another audience.

MS. SPRINKLE-VINCENT: Hello. I'm Susan Sprinkle-Vincent. I'm a mammography technologist and consultant from Houston, Texas.

I travel also like Diane all over the country training technologists, do the 40-hour initial training in Houston, do lots of hands-on positioning,

accreditation assistance, and myself, like Diane, find most facilities that I go to the technologists do not have appropriate viewing conditions.

I struggle with that a lot, especially working with them to improve their positioning skills and their technical factors, and find it a lot of times pretty impossible to do in the conditions that they are given to review their films in.

And then a lot of times unable to get into the radiologist area to use their viewing conditions because they're busy and they're tied up.

A lot of the technologists would love to see this in force so that they would be allowed or their facilities basically be forced to buy them the viewboxes that they need.

Thank you.

DR. BARR: Thank you.

CHAIRPERSON HENDRICKS: We'll take one more question from the audience and then move to the next area of regulations -- thank you -- just in the interest of time.

MR. FLATER: I'm Don Flater with the State

of Iowa, and we are an accrediting body, and we're also a certifying group.

And we do have very aggressive inspectors and we require that on every one of our facilities. So it has been done at least in the State of Iowa.

DR. BARR: Thank you.

CHAIRPERSON HENDRICKS: Thank you very much.

DR. BARR: I'm not sure how exactly to summarize this, but I think what I'm hearing is that viewing conditions, not just the luminance of the viewbox are important and should possibly be considered for some regulation in MQSA. I think that's how I'll summarize that for now.

E is eliminate the modality specific CME requirement. The recommendation, if we go to the bottom, is for eliminating the wording "this training shall include at least six Category 1 continuing medical education credits in each mammographic modality used by the interpreting physician in his or her practice.

To perhaps shorten discussion time we are,

you know, totally on board with this. We have not been enforcing the modality specific CME requirement and are totally fine with removing it from the regulation. I've heard lots of positive comments on this. So what I'd probably like to limit it to is if anyone sees a major objection to removing this requirement.

(No response.)

DR. BARR: Thank you.

I don't think we need to go through the rationale since I think everybody thinks this is a good idea.

This is 900.4, requiring review physicians for accreditation bodies to specialize in mammography. What IOM would like to have is wording that says at least 50 percent of each year's practice in breast imaging and that the physician be currently actively participating in the modality reviewed at an MQSA certified facility.

I think what IOM is trying to get to here, if I understand it correctly is that physicians who are reviewing films for accreditation should have at

least if not more experience in the modalities that they're reviewing, then people at the facilities that they're reviewing for, and I would like to hear if possible just a very brief statement from, say, ACR and, Don Flater, since you're here as an AB what you do require of your physicians looking at modalities, in particular, digital modality.

Please reintroduce yourself for the transcript. Introduce yourself for the purpose of the transcript of this meeting, please.

MS. BUTLER: Penny Butler, American College of Radiology.

CHAIRPERSON HENDRICKS: Thank you.

MS. BUTLER: The ACR requires a reviewer's practice to be in best imaging, I think we say. So --

PARTICIPANT: Modality.

MS. BUTLER: Thank you.

In the modality, yes.

DR. BARR: Okay. So if someone were reviewing for digital accreditation, their practice would be.

MS. BUTLER: I take that convoluted language back then. It would be in breast imaging, but they do have to meet -- if they were reviewing for digital, they would have to meet the MQSA requirements for digital.

DR. BARR: Thank you.

MR. FLATER: That's exactly the same for ours. In fact, we even like to use people that work for Penny to be part of our system.

DR. BARR: Thank you, and that was my understanding of what the accreditation bodies did do.

Does anyone see a problem or have any objections if something were to be added that reviewers had to meet this requirement?

DR. FERGUSON: No, I'd just say that it says "specialize in mammography" and then in quotes down there it says 50 percent. I'm one of those that I do general radiology, but over half of my practice is mammography, and when people ask me do you specialize in mammography, I say no, but I do over half of it. So just so that was clear, you know.

DR. BARR: Thank you.

This is Section 900.4, the results of equipment evaluations. With its initial accreditation application, and IOM would like us to add "the results of," a mammography equipment evaluation that was performed by a medical physicist no earlier than six months, et cetera, et cetera, I don't see a major problem with adding "the results of." Does anyone?

Charlie, do you have a comment on this?

DR. FINDER: No. I just wanted to mention that the next couple of slides really deal with a very specific process, recommendations for changes to the regulations dealing with accreditation bodies, and I wouldn't want to spend too much of the committee's time on going through in detail some of this material. If we can kind of go through it quickly, I think that would be the best thing because many of these changes we've already accomplished through changes in our procedures, and I do think we have some other issues that are more important in terms of facility issues.

So if we can just try and go through them quickly, maybe all at once.

DR. BARR: Yeah, I agree, and some of this

is minor wording. So I think we'll just flip through them, and if you see something that you think is a big issue or that you really object to, then chime in.

Again, we have wording in 900.4 to add the words "annual survey" and change the six months to 14 months.

Charlie, any issues here that people might --

DR. FINDER: I think that this works out fine for reaccreditation where under our current situation we allow facilities to have up to 14 months for the annual survey to be done between inspections. It certainly makes sense to allow that similar type time frame for the reaccreditation process so that the facility doesn't have to do two surveys within the same year.

DR. BARR: Okay.

DR. FINDER: So we didn't have any real issue with that. The wording on some of this would have to be crafted so that we don't create a problem with a new facility. We won't allow them to do things 14 months before they actually start in practice.

DR. BARR: Right.

DR. FINDER: Six would work there, but it can be worked out.

DR. BARR: I think the intent here is fairly reasonable.

And this is to delete a section of how the facilities submit their information. Any issues here, Charlie, that need to be brought to the committee's attention?

The bottom line here, I think, is the second bullet. Submission to the accreditation body each year is redundant.

Again, some minor wording changes that I think clarify intent. Charlie, any issues here?

DR. FINDER: No.

DR. BARR: And this is consistent with other suggested changes that the IOM has made.

Again, I think a minor wording change just for clarification purposes, which doesn't change the meaning. This is to make sure that facilities know that all units need to be accredited.

And, again, wording to clarify what

facilities must do when they have a new unit. I think that's pretty straightforward.

This is a section in the reinstatement policy to delete some wording. Any comment on that, Charlie?

DR. FINDER: No. Just to clarify that the way it's written it kind of gives the impression that if you reinstate you become a new facility. That is not the case, and by getting rid of those words it would make it clearer.

DR. BARR: In this case they're saying the facility retains its original ID numbers. So we don't want to reinstated facility to be considered a new facility.

This one is change to "continuing experience," and this one might require a little bit of discussion. I'm going to let Charlie sort of lead you with how it ended up this way and what we might do here because I think this one probably would engender a little bit.

DR. FINDER: Yeah. The continuing experience and continuing education requirements for

all three personnel categories are written in a similar manner, and they talk about measuring back from the date of the inspection, 24 months or 36 months depending on whether it's experience or education that you're measuring.

And the history behind it is that under the interim regulations, the requirement was that you have to have certain requirements met. It didn't give any specifics of how we were going to inspect against it or measure against it.

And what we were finding was while that I think everybody at the time those regulations were written had the idea that everybody should always meet all of these requirements, the problem that we encountered was that some of our more zealous inspectors were trying to inspect and insure that on every single calendar day somebody met this requirement because you can go back for the last two years and check every single day and see if they met it.

In order to avoid that, we by policy informed the inspectors that they were to measure it

in a certain manner, either measuring back from the date of the inspection or from the end of the previous calendar quarter or any day in between. The choice would be left up to the facility.

Well, that was in guidance, and when we rewrote the regulations, it was worked into the regulations themselves, and that's what we have here.

Now, we have gotten many times from many different sources the request that instead of measuring it back from the date of the inspection we go from a calendar date, the first of the year, making it more simple for the facilities to keep this requirement in terms of bookkeeping.

It has been considered multiple times. It was considered before we even put these in the regulations. That concept had to be weighed against the idea of do we want to make sure that everybody always meets all of the requirements all the time.

And we felt that when the final regs. were written, this was a reasonable compromise. In effect, the way these regs. were written and the guidance that's associated with it, if a facility keeps up on a

quarterly basis and makes sure all of their people meet their requirements as of at least the quarter, they will never have any problems.

This, however, would make it simpler on the facilities if we went to just a calendar date, and that's one of the things that is being considered.

Another part of this requirement that I think is very important that you need to consider is that they also say continuing experience obtained outside of the U.S. is also acceptable, and we wanted to know what people thought about that.

So there are two aspects to this, and it's very similar in one sense for continuing experience and continuing education. Do we want to change how we inspect against these requirements? Do we want to change it to a calendar date or not? And what do people think?

And once you start talking about that, I can give some more background as to what we have found in the past.

DR. BARR: Okay. So we'll start with the previous two calendar years' additional wording

instead of all the current wording that's in here. Any comments on that?

DR. FINDER: Anybody think it should change to what they're recommending, leave it the way it is?

DR. FERGUSON: I don't like the way it is. My technology --

DR. FINDER: You're in the majority then, but the question is what --

DR. FERGUSON: My technologist comes to me every time and says, "We have our inspection coming up. Now we have to go calculate," and we'll spend an hour calculating whether my hours are done according to the way they ought to be done.

And it would be simple and I don't know when you say a calendar date if you're saying January 1st to December 31st.

DR. FINDER: Right.

DR. FERGUSON: I think it would be simpler on the people checking as well to be able to look and say, "Well, in this year you had five, five, and five" or however you did it.

MS. MOUNT: Carol Mount.

I agree 100 percent. It's a nightmare trying to sort back from the date they came for inspection to try to figure out if everybody has the right numbers.

Our numbers in our institution happen to be big enough that we have kind of been doing calendar year anyway, and it works just fine for us.

DR. BARR: Charlie, again, could you just tell us quickly what the reason was for doing it this way in the first place, what the simplicity would not allow for?

DR. FINDER: Right. Some of the advantages and the reason we decided to go with the inspection date is that's when the inspector is there. The inspector can actually see what's going on, can look at the numbers, and if necessary can cite the facility.

If we go on a calendar basis, we would have the following type situation. We would hope that the facility would do what they're supposed to do on the first of January. If they didn't, however, the

inspector wouldn't be there. There would be no citation at that point. The inspector could come in 11 months later and find that on January 1st the person didn't meet the requirement.

Of course, at that point it would be questionable whether they should cite or not because by the time the person came in, the inspector came into the facility, that person probably would be up to the requirement or could be, in which case, we didn't want to cite somebody for something that happened 11 months before when they're now qualified.

So it really came down to an issue of could we -- what would be the most efficient way in order to deal with the inspection when the inspector was there, could address the records, and could make the finding at that point rather than leave it up to the facility at some point earlier in the year?

DR. BARR: What if we just used the 24 months from the date of the annual inspection and not the second part of that getting to choose or choosing a quarter?

DR. FINDER: Well, we put that in there to

give the facility more flexibility because in many cases while the facility knows approximately when the inspector was going to be there, by allowing them to go back to the end of the previous calendar quarter, they wouldn't have to rush around as soon as they got the phone call from the inspector and say the inspector is going to be here in five days, to start looking at those records then.

They could get their records set as of the previous calendar quarter when they expect the inspection to actually occur. So it was an attempt to make the bookkeeping easier on the facility.

Basically if you're dealing with a single facility what this says is you just have to figure out your numbers once a year, the end of the calendar quarter, before you expect, you know, the inspector is supposed to come in.

The real problem comes up with people that work at multiple facilities where they will be inspected at different times, and that can make it more difficult for them. Each individual facility could do this on a quarterly basis, but the individual

would have to keep their records up.

That was not felt by many on the committees in the past to be such a bad thing because their understanding or their idea was that everybody should be qualified every single day anyhow. So it shouldn't be that big a deal for somebody to document that.

But obviously there are other issues, and it's not as simple as if you just pick one date. So you have to weigh those two things.

DR. BARR: Yeah, I think it's pretty clear that the initial wording wasn't just designed to be confusing, that there were reasons.

Any ideas of how to solve this problem?

DR. MARTIN: Melissa Martin.

I don't think it's a solution, but I would reiterate what Carol said. The facilities go through great contortions to meet "oh, the inspector is coming today." The inspectors come within a 14 month period, and at this point maybe because we are a state where apparently there's been a disagreement or not a signoff, and MQSA inspections have been postponed

literally at four o'clock on the day before the inspector is supposed to be there the next morning.

The facilities have gone to great lengths to get all of their data together, and they're now told, "We're coming in six weeks," which puts them into a different quarter and they were told to redo all of their data.

Talk about an absolute waste of time. This is what's going on whether we want to acknowledge it or not. It is an absolute waste of time to gather all of this data twice. It would be much more simple just to put it into the calendar years.

DR. MONTICCIOLO: I agree. Those are excellent comments because we've been through exactly that, having to recalculate and recalculate, and we provide our physicians with their audit data on a year to year basis, and so this would match the audit data.

And I would also point out that this type of change, just allowing the use of the calendar year doesn't introduce much danger to the patients or the quality. You know, I don't expect my physicians if they do their CMEs six months later are going to

forget everything they knew up to that point.

So I think that if they want to a course three months later or whatever and just stayed in the calendar, they're going to remember it better instead of having us have to badger them because our date is coming up, a date that doesn't relate to anything in their minds and we say, "Hey, you know, you have to get your CMEs."

If they had it yearly stuck on the calendar, it would be easier for them to remember and to accommodate us. So it would be actually a benefit to go to the calendar system.

DR. BARR: Okay, and I think I'll summarize it that way.

I have to agree when I practiced under MQSA I found this confusing, and I still do, but there were reasons in mind when this was set. So summarize here that the current wording is confusing and that we should work on perhaps a calendar year process to simplify.

CHAIRPERSON HENDRICKS: There is a comment from the audience.

MR. MOURAD: Wally Mourad, FDA.

Sorry I did not bring this up earlier. I just thought of it. When we try to calculate the continuing experience and continuing education, it's always referred to the individual starting date. The starting date is the date when the individual has met his or her initial qualifications.

So for people that have met the initial qualifications several years ago, it's not an issue. But for people coming into the fold today, if a person qualified today, they become eligible for meeting the continuing requirements 24 months from today and 36 months from today, respectively.

If you do it on a calendar basis, that equation has to be changed somehow. Just be aware of that.

DR. BARR: Thank you.

Okay. So I think we get the spirit of this, and with our collective brains I think we can work on this issue.

I think the last line of this continuing experience obtained outside of the U.S. is also

acceptable. I think we should go through some of the comments on this. I don't know where the rationale is on that.

Well, be that as it may, what do people think of --

DR. FINDER: There it is.

DR. BARR: Oh, physicians who initially qualified in the U.S. under MQSA should not be prevented from using foreign experience. I think some of the things that we've heard as a concern is how do we know what's going on in these facilities.

Charlie, what have you heard on this issue?

DR. FINDER: Well, yes, we have heard concerns about using foreign experience. Under the current guidelines and regulations, foreign experience is not allowed. Our feeling was that we have no idea of what kind of quality is being put forth in those other countries. We have no idea what type of facilities they're at, what type of equipment they're using, whether there's any quality assurance at all being done, whether there's any audit procedures being

done.

And we also believe that the two-year interval that we allow continuing experience to be recorded took into account the fact that people may be going out on sabbatical, may be going out for medical reasons, may not be doing a lot for some period of time, as much as a year, and they could still meet our requirements.

We felt that there was enough leeway put in here that the issue about allowing foreign experience wasn't necessary, but that's why it's being brought up before the committee, to hear what you people think.

DR. MONTICCIOLO: Okay. Well, Dr. Monticciolo.

You know, there certainly are a lot of good mammographers in other countries, but I do think it is hard to decide how you're going to gauge quality, and I've done mammography projects in different countries, Panama, China, India, South Korea, and those are all completely different and so I would have a hard time just making a blanket statement

to allow it to be used.

Our initial requirements to get somebody to be an interpreting physician I don't think are so onerous that it would prevent people from other countries from practicing. So I don't know. It would be very difficult to gauge those levels of experience.

DR. BARR: Yeah, I'm not sure what prompted this recommendation. I don't know if there's a pressing need to have foreign experience included. On balance, I think I've heard more concerns than positives, but I don't know what prompted this.

Thank you.

Are we on closed facilities already? I'm sorry. Charlie, am I at the end of my thing yet?

This is a change to continuing experience for medical physicists, and what IOM is recommending is to take out the wording in the requirement of at least two mammography facilities and a total of, and I think we can sort of shorten this discussion.

What they're saying is it's difficult to medical physicists to provide services to more than one facility in a 24 month period. Outside consulting

is sometimes prohibited. Units' facility ratios increased, and physicists have adequate experience surveying one facility.

I'm not sure what prompted this because our current regulation is that this requirement can be satisfied by the regs. the way our regs. are currently written. So I'm not sure exactly where the issue is here.

If anybody sees where the issue is, I'd be glad to entertain it. Otherwise, any physicist want to comment on this?

DR. MARTIN: I don't think there is an issue.

DR. BARR: I thought it was pretty clear, but obviously it wasn't clear enough.

CHAIRPERSON HENDRICKS: Comment from the audience on that?

MS. BUTLER: Penny Butler from the American College of Radiology.

One thing that prompted this is that there were physicists at large institutions with a large number of units, and because the way the regs. are

written, that they provide services at two facilities. Sometimes by their contract they're not allowed to practice outside their own facility. So they would have to really be forced to providing services someplace else in order to meet the regulations.

DR. BARR: But you can't do it by being at a single facility. You can meet the requirements.

DR. FINDER: Right. This is Dr. Finder.

The regulations allow the medical physicist to do a survey. It's a requirement, two facilities and six units over two years. So by doing the same facility twice in the two-year period, which you are allowed to do, one each year for the surveys that are necessary anyhow, you would meet that requirement.

The same for the number of units. We do allow -- for example, a medical physicist who is in a facility that has only one unit can by doing two surveys and resurveying the unit as much as every 60 days can actually meet this requirement at one facility.

MS. BUTLER: Okay. If that is, indeed,

the intent, although I don't recall that from the original regulations, and I'm pleased to hear that interpretation; then if that's indeed how it's being interpreted, I think it's --

DR. FINDER: Well, yeah.

MS. BUTLER: -- it's right the way it's written.

DR. FINDER: All right. It's written that way.

CHAIRPERSON HENDRICKS: Dr. Williams.

DR. WILLIAMS: This is Mark Williams.

If that's truly the intent, then why is the word "facility" even brought into it. Wouldn't it be clearer if we just took it out?

DR. FINDER: No. Actually it probably wouldn't because the idea here is that there's a difference between the survey of a unit and the survey of a facility. There are different aspects to both. So if you just did unit surveys, you wouldn't look at the QC for the entire facility, and that's part of what is required for the annual survey.

So that's why it was specifically written

referencing two facilities and six units, but they all can be done. It can all be accomplished in as small a facility as a single unit facility.

DR. WILLIAMS: So would there be some merit in explicitly putting that in?

DR. FINDER: It is. It says here, "No more than one survey of a specific facility within a ten month period or a specific unit within a period of 60 days can be counted toward this requirement." That's in the regulation.

We thought it was clear. We also put it in our guidance, too. So it is possible for a physicist who cannot work outside his one facility to still meet the requirements. They don't have to go anyplace else.

DR. BARR: Clearly, we all believe in the spirit of this. We can look at it and see if there's any way the wording can be any different, but the interpretation is as we've said.

Thank you.

The next is changes to the lead interpreting physician requirement, and IOM recommends

adding language that the lead interpreting physician must provide regular feedback to technologists on the quality of images. It seems to me that was already their job, but I guess this makes it more explicit.

DR. FINDER: Actually there is a requirement that all interpreting physicians have to give feedback.

DR. FERGUSON: Does that have to be documented in any way? That's the problem you get into.

I mean, we interact every day and say this looks bad, this doesn't, but if you come in and want a piece of paper saying, "Where did you document that you did that?"

(Laughter.)

DR. FINDER: Dr. Ferguson, I know you must tell them this looks good and this looks better.

(Laughter.)

DR. FERGUSON: No, sometimes it's pretty rough.

DR. BARR: Yeah, I don't think there was any requirement that this has to be documented. I

don't know if that's what IOM was trying to get at since already this is a requirement. Anyway, I think obviously the spirit is that people should be communicating with facilities to get better mammography.

The rationale here was the on-site surveys. ACR does suggest facilities could benefit from improved physician technologist communication. As my kids would say, "Duh."

And requiring regular feedback may improve quality.

Next is changes to weekly phantom image, quality control test. This would be a change in the optical density of the film at the center of an image of a standard FDA accepted phantom, and it would delete 1.2 and change it to 1.4 when exposed under typical clinical condition.

Yes.

DR. MARTIN: Melissa Martin.

My only comment would be why are you leaving it at 1.4. Shouldn't it be at least 1.5?

DR. BARR: Well, you'll have to ask IOM

that. I think the point is well taken about --

DR. MARTIN: One, point, four is way too low.

DR. BARR: I'm not sure why they picked this number.

Anybody else have comment?

So we think it should be at least 1.4 is what I'm hearing.

Okay. Rationale seems pretty logical.

Screen film contact. They want us to take out the word "semi" and put in "annually," and the test shall also be carried out initially for all new cassettes as they are placed in service, and whenever reduced image sharpness is suspected.

The rationale is that this only needs to be performed annually or on new cassettes, and we already have guidance on this that says screen film content tests must be performed on new cassettes prior to clinical use. So I think we're okay here with what IOM intended.

Change to kVp accuracy and reproducibility. They would like us to add facilities

with older three phase screen film systems. Take out the end reproducibility part. Take out the most commonly used clinically part, and say that is obtained when the accrediting body phantom is imaged with the mammography X-ray unit set to the most commonly used clinical AEC mode.

And take out the wording in the orange on the kVp and add newer units with medium and high frequency generators will not require this test.

They feel the phrase "most commonly clinically used kVp" is confusing. Data from DMIST shows test really fails during the annual survey. Equipment voltage regulation is tight. Unnecessary on an annual basis.

Anybody have any comments on this area?

DR. MARTIN: Yes. Melissa Martin.

I would agree that I have no problems with that recommendation. The biggest problem we would have is if you tried to enforce the kVp. That does fluctuate on some models, but obviously if you're going to eliminate it for high frequency generators, you just eliminated it on 95 percent of the units. So

it's a moot point.

DR. BARR: Okay. System artifact test. They want us to take out tees and target filter combinations and add targets and filters used clinically. The rationale to assess image quality and artifacts, only one test of focal spot size, filter, and target is necessary.

We already have an approved alternative standard for this. So again, I'm not sure what the recommendation is made for, but I think we're okay with this, that we don't have to do all of the combinations.

This is changes to mammography medical outcomes audit. They want us to add facilities with the same interpreting physician should combine medical audit data. I think we kind of covered this earlier in the audit section, that we should allow that combining of data. to make things more meaningful.

And again, they recommended that people not be cited for not doing aggregate data.

Changes to mammography medical outcome audit. The general requirement section they want us

to take out "individually and collectively for all interpreting physicians at the facility." I guess that's so we can combine data, and add this whole section here.

A screening exam or a positive exam is defined as incomplete or suspicious or highly suggestive, and diagnostic exams or a positive exam is defined as suspicious abnormality. Biopsy should be considered. And diagnostic exams where positive examination is defined.

Again, this is all rationale for combining data. Not being able to compare facility practice performance with literature.

The BI-RADS committee said the audit of screening examinations requires recommendation for recall, including Category 0 be considered positive, and it would make the regulations more consistent.

Any comments here, Charlie? Anything that can help a discussion here?

DR. FINDER: Well, we pretty much discussed this earlier, at least some of the aspects of it, and I just want to hear what people think.

I mean, here they have defined screening exams and diagnostic exams, and we have the whole debate about can we do that, should we do that. If we can't define it, it becomes very difficult to write a regulation that talks about those as examinations.

The other thing I found interesting in the way they have it worded -- and I'm not sure if they meant this -- but the way it sounds here is that if you read a diagnostic examination as incomplete, it doesn't have to go into the audit.

Now, maybe I misread, and I doubt it's what they meant.

DR. BARR: Right.

DR. FINDER: But there's nothing that prevents anybody even right now from labeling a diagnostic examination a zero.

DR. BARR: Yeah, I had the same comment on my notes. What about a zero? Isn't that a positive? I thought they already defined that as a positive.

DR. FINDER: And, again, this issue about the screening exams, this would increase the work load for facilities because they'd have to track the

incompletes, which could be a fair number, and that also brings back the issue of the incompletes due to comparison with old films versus the additional studies.

So anybody have anymore comments other than what they've already discussed earlier? Is this something that we should put into regulation at this point or should we think about it a little bit more?

CHAIRPERSON HENDRICKS: Comment from the audience? Yes, Dr. Monticciolo first.

DR. MONTICCIOLO: I have to put my glasses on. This is Debbie Monticciolo.

Well, I am reiterating what was said earlier. I do think it would be onerous to have to follow ever zero. I mean, we do ourselves make sure every patient we ask for additional imaging, we make an attempt to get them back and make sure they know they need it.

But to follow all of those to whatever you consider the outcome would be very onerous for any screening site to do, and specially if you include the zeros. So that was actually very well put, Dr.

Finder, that I think this is a huge burden, another burden, that we're going to lay on screening sites, and I don't think it would be that productive.

DR. BARR: Okay. Thank you.

Next is Section 900.13, change to FDA action following revocation of accreditation. This is really just a wording change that needs to be done and we agree with.

Okay. Modifying inspections and strengthening enforcement. Under this section IOM said that FDA should eliminate several on-site inspection tests, such as dose and other radiation tests; should require the facilities to cease performing mammography after two consecutive unsuccessful attempts at reaccreditation even if the MQSA certificate is still valid; that we should require a facility that closes or has its certification revoked to notify patients and referring physicians; and regulations for film retention should apply to closed facilities.

So we'll take the first one. Several on-Site inspection tests are redundant and have few

failures, and we talked about dose. We haven't had a dose violation since 1997. Dose testing is monitored by ACR and the medical physicist. Other tests are already done by the medical physicist include beam, quality X-ray, film alignment, et cetera.

Again, this just shows you what Mr. Divine showed you about the violations or lack thereof, and we did hear the comment before about possibly looking at the scattering of the dose data around what we currently consider upper limit of normal.

The one thing that didn't come up earlier, I think, related to dose is that you think, well, big deal, the inspector going and modifying it, and if you don't measure dose, is it really going to cut down the inspection time?

But we also have to buy, calibrate, maintain equipment for the inspectors to perform those measurements. So that's another just piece of the pie here.

And the objections I have heard are, as I've said before, about the disparity between the physicist and inspector's measurements, but we're

looking at that and I don't expect that to be the case, but we'll see.

FDA should have the authority to require facilities to cease performing mammography after two consecutive unsuccessful attempts at reaccreditation. Our legal eagles here tell us that FDA cannot require facilities to cease mammography if their MQSA certificate has not expired.

Charlie, do you want to lead a little bit of this discussion on this?

DR. FINDER: Right. Again, some of the background on this. Usually this situation occurs when a facility is coming close to the end of its certificate. It's in the reaccreditation process, and it doesn't pass the accreditation process.

Our lawyers have told us that that process deals with the next three year accreditation and certification, not with the current one. What they have told us is that we cannot automatically tell the facility that they must stop doing mammography based on their failure to get a new accreditation.

We can tell them that they should stop.

They must stop when their certificate expires, and they have told us that if we feel that they represent a risk to human health, we can take action either to suspend their certificate if necessary.

So what they've told us basically is you cannot take actions against the facility more severe than you would for a suspension, and in most cases when we suspend a facility, we have to give them notice. We have to allow them for a hearing, and they have told us that you cannot just because they don't pass the accreditation process for their next three years automatically tell them to stop where in a situation where the accreditation body tells you that they represent a risk to human health, a much worse situation, you have to give them a legal process to go through.

We certainly have that ability in these situations to take that more extensive action, but the reality is that by the time we could actually suspend a certificate under those types of circumstances, their certificate would have expired anyhow. Usually it's a matter of a few weeks at most, in most cases.

So this is true, and the recommendations from IOM that we put ourselves or grant us the authority in regulation certainly would address this situation. I'm not exactly sure that we could still do it because we cannot put in a regulation that negates the entire appeal process, the entire process for a hearing. So I'm not sure we could even implement it even if we tried to write a regulation.

But that said, I think the concept of is this enough of a problem that we should try to develop some method for dealing with it or is it so self-limited that we should just pretty much leave it the way it is and let the certificate expire, understanding that these are facilities that we have no indication that they represent the risk to human health. It's just that they didn't pass their accreditation process.

So comments, thoughts?

(No response.)

DR. FINDER: Okay. Moving on.

DR. BARR: And the other recommendation is close facilities or facilities with revoked

certificates must notify patients and referring physicians. Film retention should apply to facilities that close.

IOM says the complaints from patients who were not informed when their facility closed and were unable or unsure how to access mammography records. If facilities are incapable of notification FDA should notify patients and physicians.

Again, I totally sympathize with patients in this situation. We take an active role with the accreditation bodies in helping patients in this situation, but again, I don't know what authority we can have over a closed facility who's out of business. I don't know what exactly we do to make them do these things.

Charlie.

DR. FINDER: Yeah. Dr. Finder speaking.

This is an issue that come sup not that infrequently, and it can be a big impact on patients, but then the question is what can we do under certain circumstances.

Let me backstep. We have guidance out

there to inform all facilities that when they are planning to close what steps they should take, and one of the major steps that they should take is to make arrangements for the retention of records and mechanisms so that patients can access those records, and most facilities do that.

We also ask that the facility notify their accreditation body of those steps and also the FDA so in case anybody asks either the accreditation body or contacts us through our hot line, we can tell the patient what steps they need to go through to find their films.

And those systems do work when we have cooperative facilities. However, when we're dealing with a facility that has gone bankrupt, it is very difficult to deal with those situations. Sometimes there's nobody we can talk to, nobody to reach. Sometimes the records are now part of the bankruptcy hearings and are outside of our jurisdiction. If we can find a sympathetic judge and explain the situation, they have in the past made some type of arrangements.

But, again, it's outside of MQSA. It's outside of the facility's hands because they no longer control the films. They're now in the hands of the bankruptcy court.

In other situations, we have the case where the facility has disappeared. We have no idea of what's going on. The films are gone. The facility itself no longer exists, and while we would like to notify patients of this, we have no information to give them in that situation other than to tell them that their films are gone.

So this is a very tough problem when we're dealing with a truly closed facility, and we would certainly like to hear from the committee about any suggestions they may have about what actions we can take under these conditions, and if there's any way to help the situation.

But there's no question that when a facility goes out of business and doesn't take care of the records and goes into bankruptcy or just closes its doors, shuts the doors, locks them, and disappears, that there are problems for patients. The

question is what we can do at that point to help them.

DR. MARTIN: Melissa Martin.

Just a question. Is there any way that you track the physicians, the radiologists tied to those facilities that have closed? So that, in other words, he can't close the facility on one corner and go down the street and open the facility on the next corner and start out as a new entity?

DR. FINDER: Right. Usually in the situation where you've got a physician or facility that has multiple locations, what they'll do in those cases is they'll just transfer the films to the other locations. Those are usually not the problems that we have.

It's individual facilities that go out of business or we have had facilities that have multiple sites where the entire organization went out of the business all at once and affected 100,000 patients.

The interesting thing is that most of those are not mammo patients. These are usually large radiology practices or medical specialty practices. It's not just the mammography records.

We have in those cases worked with the state because they have their own state laws that they can enforce sometimes, and they find it very difficult, too because if they're gone, they're gone. It's very hard to track some of these people.

DR. BARR: I know some states have a requirement that facilities put a bond in case this happens and they can use the money, and I'm not sure at the federal level if we can do that.

I'm wondering if this is something just to make it work really needs to be a state issue.

DR. FINDER: Again, if anybody has any other suggestions, we'd be more than happy to hear about it because, as I say, it's infrequent. When it does occur, it's not pleasant for anybody involved.

DR. FERGUSON: You said there was guidance out there. What is the recommendation for a facility that is closing?

DR. FINDER: The recommendations that we have basically are that the facility inform the state, inform our facility hot line that they're closing; that they make arrangements for those films to be

available. And what we suggest is the first suggestion is that they be transferred to another actively and active mammography or radiology facility so that patients can go there and get those films.

If that's not available, we suggest that they go and put them into some type of storage facility where the patients can have access, and as part of that, it's very important that they have some mechanism to inform their patients of what's going on so that it's not just that they do this and nobody knows about it so that patients can't get it.

So we suggest that they have either something on their phone line, an answering machine that gives this message out or that they send out some type of notification or at a minimum that they notify their accreditation body and us so in case patients call us we will know how to forward that information along.

So those are the basic recommendations to the facilities that close. The problem is that if they don't, there's not much we can do after the fact.

MS. RINELLA: Question. Diane Rinella.

What percentage of time do you find that this happens where they actually truly notify that they are going to close versus just closing the doors and going?

DR. FINDER: I can't give you actual numbers. I do know that we get in the mail from facilities this type of information. I can't give you the exact numbers. I will tell you that the number of facilities that close and leave problems like this is a relatively small handful, but when it does occur even at a small size facility, you're probably talking about thousands of patients being affected. So in that sense it is a big issue, and we have had some major facilities that have closed where I think at most there was a group out in California with millions of records, but most of them were not mammography. They were everybody's exams, CTs, medical records of all kinds.

So it's more than jut mammography, and we found that that's usually the case. It's not just a single mammography facility that closes down. It's either a radiology practice so that you've got other

patients that aren't even affected or don't have any recourse to us at all for those exams.

MS. PURA: Dr. Barr, that suggestion you had about the bond issue, have states done that before?

DR. BARR: I believe that there are states that have done that. I'm trying to recall. Michigan comes to mind, but I don't want to speak out of turn that they have done it.

We have worked with states and some state have done that. But as I said, at the federal level I'm not sure that that's an option.

Charlie, do you remember?

DR. FINDER: I'm not sure about which, if any, states have instituted a bond. I know that it has been talked about even at this committee, and one of the issues that was brought up is if you're going to have all facilities post the bond when they start, that's another disincentive. It's another issue about, another burden on the facility, considering the fact that the vast majority of facilities that do close do take care of this issue appropriately without

anything.

DR. BARR: And I think that's something we have to keep in mind. Since we deal in the public health, we also have to look at is the energy spent on this, although it is very adverse to the patients affected, you know, how do we deal with it in a public health sense and is it a few bad actors and would the state be better able to deal with this and also it's a difficult problem.

MS. PURA: Oh, I know because we go through it quite a bit in Los Angeles and of late it has been a major problem.

DR. FINDER: You know, there are two aspects. One is do you put some type of requirement on all facilities with the idea that in the event that if this happens you can then use that as a fund to accomplish something, although even there you're never 100 percent sure because when they close, we have had the following situations happen where they have their records in some type of filing system that is well known to them. Of course, they're no longer around, and now you can't even categorize these films anymore

and hand them out even if you could.

The other is to try and take action against the people that have gone and closed shop, and as I say, when possible we have tried to deal with the bankruptcy court, and in the cases where we have been able to deal with them, they have been receptive and taken some actions.

The states also have power in this area, and recently we did have a state go after a facility and force them to reopen and distribute the films. So it can be done. It's a very tough problem, and I think, as Dr. Barr mentioned, probably our best bet right now is to try and work in conjunction with the state to deal with these problems, but it is a tough one.

DR. BARR: We were just hoping someone would have a brilliant idea we hadn't thought of yet.

And despite Dr. Finder's being sure I wouldn't get done, I finished the section before the break. So, Dr. Hendricks, is it time?

CHAIRPERSON HENDRICKS: I think it is a good time. We'll take a 15 minute break and reconvene

at quarter till.

Thank you.

(Whereupon, the foregoing matter went off the record at 3:28 p.m. and went back on the record at 3:50 p.m.)

CHAIRPERSON HENDRICKS: We'll reconvene for the final session this afternoon, which is Dr. Barr on a marathon leading us through the two final topics on work force and beyond mammography.

DR. BARR: Thank you.

I will try to get through this last section. I need to leave here about 4:30-ish. So if we're not finished, then either Mr. Divine will come up here and continue or Dr. Finder can switch seats, but we'll see what we can do.

The next major category for recommendations from the IOM report falls under adequate work force for screening and diagnosis. Under here are Recommendations 7, 8, and 9.

Recommendation 7 is to collect and analyze data on the mammography work force and service capacity; eight, device strategies to recruit and

retain highly skilled breast imaging professionals; and, nine, make more effective use of breast imaging specialists.

And we'll start with data on the mammography work force and service capacity. IOM recommends that volume information be collected during annual inspection. HRSA reports on mammography volume by region, state, and type of service. And I think they mean that their reports, which we could contribute to, should include number of facilities, number of mammography units per 10,000 women, number of FTE physicians reading mammograms per 10,000 women stratified by type of service where appropriate.

That we provide unique identifiers for all interpreting physicians, technologists, and medical physicists to get volume services by individual.

That we collect data by facility and waiting times for screening and diagnostic appointments.

That Congress, I assume, not FDA, provide funding to HRSA to model future work force supply and demand on a regular basis.

And the rationale for these recommendations which then we can go back to is to be able to assess accurate real time data to monitor and track capacity on a national and regional basis; to be able to assess the status of the work force; assess appointment waiting times, and assess impact of new regulations and voluntary programs.

So we'll go back to the volume information. Currently the information we have on volume is provided by the facilities to their accrediting bodies on an every three year basis when they apply for reaccreditation, and I don't know how it is in other facilities, but I can certainly tell you when I was practicing, I didn't write down on the form an exact number. I would certain give my best guesstimate of the number of mammograms we performed.

So it has always been debatable how accurate the information we have when we are asked to give volume statistics.

I don't know if that would change if the inspector was asking the question versus the accrediting body, but we'd like to hear your thoughts

on how important this information is and the best way to collect it.

Okay. No comments? Okay. Yes?

MS. PURA: Would this invitation by any chance be helpful to such as the CDC, et cetera, to expend monies for reimbursement if we knew that there were so many mammogram units per facility, et cetera, across the country and the ratio of staff to -- do you think that would be helpful, Dr. Barr, or do you think that would be helpful?

I'm always pushing for reimbursement.

DR. BARR: It's really hard to gauge. I myself have been to CMS talking about the costs of at least meeting MQSA regulations if nothing else, and it doesn't seem to affect their reimbursement.

You know, certainly one would think intuitively that more information would inform them to make decisions, but I can't say for sure.

DR. FERGUSON: Does ACR not already kind of have this information about facilities and locations? Would it be easy for them to, I guess, interpolate the number of patients in a geographic

area?

DR. BARR: I think the volume information they have is through facilities, but we'll let Penny. I mean through facilities on the accreditation form, but we'll let Penny comment.

MS. BUTLER: Penny Butler from American College of Radiology.

We do collect information, but they're annual patients examined and breakdowns between diagnostics and screens, but we don't have really good, reliable FTE information and some of the other information that is asked for here.

DR. BARR: And certainly asking a volume question during inspection is not a big deal. I mean the inspector could spend two seconds asking that. I think probably the bigger issue here I would say is this unique identifier information. I mean I think that's really where it's at if we want to get some of the data that's being recommended here.

Some of the data that's being recommended here, I can say that from our standpoint there is the problem that if we go to a unique identifier system,

then our database has to meet the Privacy Act requirements which it does not have to because we collect data based on facilities. We search by facilities.

And so there would be work and possibly financial burden associated with that. The other thing is, you know, the whole discoverability stuff. Could this be tied into how much mammography you do and what your results are, et cetera?

So just be anxious to hear your comments on B, the unique identifiers, so that we can get volume by individual and perhaps other data.

MR. PASSETTI: Bill Passetti.

I just think it would be nice if some of this standard information was collected on a nationwide basis. In Florida we're having a situation where our legislature is looking at mammography accessibility and different things, and they're already talking about requiring us to collect volume data or how many exams are performed per machine and all this type of data that would be nice to have, but it would be nicer to have on a nationwide basis and

not just our state.

DR. BARR: Right. Understandable.

DR. MARTIN: I would just like to -- Melissa Martin -- to take an idea. If you're developing a database to collect this data, put the thought in that if you're going to assign all of the providers' unique identifier numbers, it would also be the option of providing at least on an optional basis the qualifications so that we don't have to kill the trees and provide that.

If we're going to be qualified, then give us one qualification, that we've got all of our CEUs and continuing experience every two years and update it so that we're not having to copy all of the paper work for every facility. Either our physician is going to be qualified or our physicist is going to be qualified or our technologist is going to be qualified.

We're qualified once. It's not going to matter where we're qualified in 15 different facilities.

DR. BARR: Thank you.

DR. FERGUSON: I agree. That was brought up at our last meeting as well. There ought to be a way where we don't have to produce every piece of paper at every facility and have a book that thick. It would be helpful.

CHAIRPERSON HENDRICKS: Comment from the audience?

MS. WILCOX: Pam Wilcox, ACR.

I think there's more complexity to this than even what we're talking about here because even if you look at interpreting physicians and you look at their screening and diagnostic volumes, that doesn't address the capacity of the system because you still have those who are doing biopsies and those who are not doing biopsies. You have patient mix.

There's a whole lot of variables that would make this -- although really it would be great to know and be able to predict where we need to be and what we need to recruit, I'm not so sure it's as simple as it seems even here.

DR. BARR: Thank you.

MR. MOURAD: Wally Mourad, FDA.

During inspections we do download during the previous inspection where a certain person has met the initial qualifications or not, and so those are there, and we don't recheck them every time except for expiring items, like license or approval letter or something like that.

So the only thing we check on continuously every time that's different is the continuing requirements, education and experience. We don't have a database for that. That's the other thing.

DR. FINDER: Right. Dr. Finder.

I just wanted to also mention that for medical physicists because we consider them a special group of -- no, we don't.

(Laughter.)

DR. FINDER: Because they do go to so many different facilities usually, much more than the other personnel categories, and because their requirements tended to be more complex in terms of the documentation that they need, we actually will supply medical physicists a letter stating that they meet all of the initial qualifications, and all they have to do

is show that letter to any of their facilities. Give them a copy of that letter, and that is acceptable for all their initial qualifications.

So we have attempted to address some of those issues through that mechanism. We have looked at the issue about having a database with individuals. It does raise a number of issues. One is how do you identify them.

You'd have to assign numbers. It would become a privacy system, but even more so than that there is the issue about how do you get the data in; who do you give that data to; and even if you were allowed and we could figure out a mechanism to give it to our inspectors, what would be the mechanism to give it out to the facilities because it wouldn't do much good if our inspectors knew that you were qualified, but when you showed up at the facility you had no documentation and they would have no way of verifying that.

That's one of the situations we've got right now with the hurricane where people have no documentation. They're showing up at new facilities,

and we in this case are providing them with some documentation because of the problems that they have encountered, but we don't give it to the facility.

And then the other issue is how would we deal with the situation where somebody doesn't give us the information at some point in time. What would we do then? Would we search them out and cite them in all of the facilities that they're out because they haven't provided us with data?

So the reason that it keeps coming up is because it would certainly be more convenient if we had this type of system, but there are always these problems that come up that seem to make it difficult to actually implement. And I guess at one point we can take a look at this, have a meeting, and discuss this in detail to see if we can actually implement something like this, but it's not very simple to do.

MR. FLATER: Flater with Iowa.

Just a couple of points. Number one --

CHAIRPERSON HENDRICKS: I want to remind all of the speakers at the microphone to please identify yourself for the purposes of the transcript

being prepared of this meeting.

MR. FLATER: Flater, with Iowa.

Just a little bit of a point. Us small people that do everything, including accreditation and certification do have all of the information you're talking about on every place in the State of Iowa, and some physicists outside the state that come in and do some work within our state.

Another thing you might want to look at is the new thing being set up by the Nuclear Regulatory Commission where they're tracking all kinds of sources and everything. There are systems available that will track everything everybody does.

DR. BARR: Thank you.

Recommendation 8 is for strategies to recruit and retain highly skilled professionals. First is to encourage federal and state agencies and health care payers to develop incentives to recruit and retain skilled breast imagers.

Loan repayment awards through the National Health Service Corps, and for J-1 visa waivers for physicians working in underserved areas.

And, again, HRSA should identify and designate shortage areas for breast imaging.

IOM says that existing supplied physicians who read mammograms are high level performance, is a valuable resource, is unproductive to invest in efforts to increase the number of entrants without addressing factors that lead to early departures.

Retaining highly skilled practitioners should be cost effective way to maintain high quality breast imaging services, and the NHSC program that J-1 waivers have been used to bolster work force in other shortage areas.

I think we've heard some of this throughout the discussion today. I think when Dr. Lee from NCR spoke, she addressed some of these issues, as did Dr. Bassett.

Are there any new thoughts about what incentives would work to recruit and retain qualified personnel? Anything that we may be able to do to stop this steady bleed of people leaving the field or not going into the field?

Okay. No new ideas. Again, a tough

issue, but certainly what we've heard is that more burden would not help the situation.

IOM says we need to encourage federal and state agencies and health care payers to develop incentives. I think I already did that. Sorry.

IOM says we should support the radiologist assistant training programs and new roles for radiology assistants in breast imaging; that this career option for skilled technologists is an incentive for new entrants and could improve quality, productivity, and efficiency.

And I know we heard at least one, if not more, comments in the public speakers on this. I'd be interested to know if the committee has any thoughts on the radiology assistant area, particularly related to mammography.

Anybody here have experience? Anybody using this type of --

MS. RINELLA: Diane Rinella.

I don't know if any of the radiology assistant programs to date have a specialty for breast imaging, and something tells me they don't, and for

right now, the radiology assistants are going through a very comprehensive program for two years for fluoroscopy. You know, so barium enemas and whatnot, and somebody that wants to focus on breast imaging, I don't think that that's something that they would need to or even want to go through.

So I would think that there would need to be something if the RAs were going to be used in the future. A training program specific, an RA format for breast imaging technologists.

DR. BARR: As a technologist and someone experienced in this field and talks to a lot of technologists, do you think that something like this program to go into would make the field more enticing?

MS. RINELLA: It really is very new still. A lot of techs out there still don't know what an RA is, but I have been to I would say a handful of facilities, and the text word going to -- that was one of their goals, go through the RA program -- but it was to become a full blown radiologist assistant. It really wasn't something that was dedicated to mammography.

So I can't speak on just specifically breast imaging.

MS. MOUNT: Carol Mount.

I don't specifically at our facility. There are about three that are just finishing up their bachelor program, and breast imaging is what they would want to do. They've had a lot of questions for me. Of course, I do not have the answers as to what would they be able to do once they were in that field.

And I agree with Diane. There would need to be a specific modality training course in order for it to be effective.

DR. BARR: Thank you.

CHAIRPERSON HENDRICKS: Dr. Monticciolo.

DR. MONTICCIOLO: Debbie Monticciolo.

I guess I have a little bit of a unique perspective because I have worked with a radiologist assistant in a private practice in one of my past jobs, but I would say that I think unless the technologists are willing to accept the medical legal burden, that many radiologists would be, I think, hesitant to pay another individual to help them, but

not take the legal burden because that's a huge issue for radiologists.

I don't know if I should say this or not, but I guess I'll just go forward. I worked with a radiologist assistant, and he was very good. I thought he was excellent and was an asset to our practice, but I believe that he was over-utilized by some of the radiologists, and that the radiologists didn't oversee his work as closely as you would expect.

And so that also is another side of this issue that would probably need to be looked at.

DR. BARR: Thank you.

Can ACR help us out on this?

MS. WILCOX: Kim Wilcox, ACR.

There has been an agreement to the responsibilities of a radiologist assistant, and that has been agreed to by the American Registry of Radiologic Technologists, which will be the certifying agency, the American Society of Radiologic Technologists and the ACR, and there will be no interpreting on the part of the radiologist assistant.

So while they might be able to help in the biopsy area or some of these other areas, I'm not sure what they would do to help the radiologist shortage that we have in breast imaging right now.

And as was said this morning and as Debbie reiterated, the medical liability issue is huge.

DR. BARR: Thank you. That really helps a lot.

DR. FLATER: Flater with Iowa.

Number one, if we did anything with the radiologist assistant, we would have to completely change our rules because interpreting physicians in Iowa must be radiologists. There's no choice.

The other side of it that's coming up that we're going to talk to later is in the stereotactic. Dr. Finder has just spent some time with us in Iowa because we have an RA in training right now that is trying to get us to agree to allow him to go through the training program to do stereotactic. There are radiologists that are willing to do training.

So that's an issue we're trying to deal with right now. Today we wouldn't allow it.

DR. BARR: Thank you.

MS. PURA: Dr. Barr.

DR. BARR: Yes.

MS. PURA: Linda Pura.

DR. BARR: Oh, I'm sorry, Linda.

MS. PURA: You know, these are the growing pains that physician assistants and nurse practitioners had in the past, and we all know that, and certainly this might be something to look at to give futuristic kind of career growth for the rad techs, and I don't know if they're not allowed to interpret at this point now, would they be able to do secondary reading for the double reading? Would that be a possibility?

DR. BARR: I think those are all good points, and it sounds like in this area we probably don't have enough information yet of how this is going to and how these people can possibly help us in the mammography area.

So I think as this goes on we'll certainly have to keep an eye on this program and see where it can possibly be of use to radiologists and as an

incentive.

Good points. I think we have models probably of other professions having gone through this. It's a good point.

IOM says that support should be given to demonstration projects to evaluate potential for double reading by non-physician clinicians, and again, this is based on the rationale that double reading has the potential to improve interpretation and perhaps that's an area where the RA would fit in.

And to evaluate the roles of ancillary personnel and mammography, productivity will be maximized according to IOM if radiologic technologists focus on performing mammograms and interpreting physicians' focus on interpretation, ancillary personnel, technical and nontechnical responsibilities, including quality control and administration.

Now, when I first read this, I was like, "Well, gee whiz. You know, we have this whole QC tech thing where you have to be in this area," but I'm not sure that's exactly what they mean.

Charlie, I know when you read this, you had a little different thought about what IOM might be saying here.

DR. FINDER: Well, I think what they're trying to get at is the idea of basically having the radiologic technologists spend all of their time doing patients, interpreting physicians just doing the interpretations and leave any of the other paper work, quality control areas to nontechnologists, nonprofessionals or nonpersonnel, as we define personnel.

DR. BARR: With oversight.

DR. FINDER: Including quality control because we do allow personnel or people other than RTs to do the QC procedures. As long as they're under the supervision of a quality control technologist, other people who have received adequate training can perform these various tests.

So I think what they're trying to get at is they realize that there are shortages for the techs and for the physicians, and to focus them on just doing the aspects of mammography that only they can

do.

DR. BARR: And as you say, MQSA does allow for this oversight type of responsibility at the current time.

Next is this new topic is improving breast imaging quality beyond mammography. Any comments on any of the personnel incentives before we move on to these final comments?

(No response.)

DR. BARR: Okay. Recommendation 10 in the report is accreditation for non-mammography breast imaging modalities, such as ultrasound and MRI. The rationale is accreditation already exists for breast ultrasound and general MRI and a breast specific MRI accreditation program is under discussion.

Accreditation for breast imaging methods would lead to standardization and improved quality of breast cancer detection and diagnosis.

I think we heard earlier in some of the talks that the MRI accreditation or anything in federal regulation of breast MRI probably isn't in the immediate future, but that perhaps breast ultrasound

is an area for exploration.

Any comments from the committee?

MS. RINELLA: Diane Rinella.

I am also RDMS in breast ultrasound and in my travels I do question the facilities and who is doing their breast ultrasound examinations, and I asked what type of equipment, what types of transducers and things that they're using, and it's unfortunate that they aren't all up to the same standard of care.

And so I would support standardization of and accreditation for breast ultrasound just because of what I'm seeing out there in the field.

DR. BARR: Thank you.

Anybody else?

(No response.)

DR. BARR: I guess that's it. Yeah, I think that's it, except for the stereotactic section, which we'll discuss tomorrow. The recommendations, I think we've pretty much gone through the recommendations.

One thing I wanted to point out is that

the final printed version of the IOM report actually just came out. So although there are no major changes, there could be like when Penny Butler was up here talking about the BI-RADS thing. There could be wording changes that in the draft were one way so that we have them on our slides, but in the final report have come out slightly differently.

Charlie.

DR. FINDER: No, I just want to say the version that you have is the current one now.

CHAIRPERSON HENDRICKS: That's going to bring to a conclusion a long day.

I do have one housekeeping detail. The woman who is transcribing the meeting has had difficulty throughout the day today understanding the names of the speakers who have come from the audience. So she requested of those speakers to get full recognition of your comments just stop by her desk to clarify the spelling of your first and last name.

Thank you.

Otherwise, this concludes the meeting, and we will reconvene again tomorrow morning at 9:00 a.m.

(Whereupon, at 4:18 p.m., the meeting was adjourned, to reconvene at 9:00 a.m., Tuesday, September 27, 2005.)

CERTIFICATE

This is to certify that the foregoing transcript in the matter of: National Mammography Quality Assurance Advisory Committee

Before: DHHS/PHS/FDA/CDRH

Date: September 26, 2005

Place: Gaithersburg, MD

represents the full and complete proceedings of the aforementioned matter, as reported and reduced to typewriting.